

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-1008V

Filed: December 20, 2023

VICTOR JOHNSON,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Special Master Horner

Leigh Finfer, Muller Brazil, LLP, Dresher, PA, for petitioner.

Parisa Tabassian, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT¹

On August 13, 2020, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2018),² alleging that he suffered the Table Injury of Shoulder Injury Related to Vaccine Administration (“SIRVA”) in his right shoulder following an influenza (“flu”) vaccination that he received on September 20, 2017. (ECF No. 1.) On November 21, 2021, an amended petition was filed adding a claim based on causation-in-fact. (ECF No. 25.) For the reasons set forth below, I conclude that petitioner is entitled to compensation for a shoulder injury caused-in-fact by his vaccination.

¹ Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10, *et seq.*

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. § 300aa-11(c). Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a “Table Injury.” That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the “Vaccine Injury Table,” corresponding to the vaccination in question, within an applicable time period following the vaccination, which is also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. See § 300aa-13(a)(1); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a).

As relevant here, the Vaccine Injury Table lists a SIRVA as a compensable injury if it occurs within 48 hours of vaccine administration. See § 300aa-14(a), *amended by* 42 CFR § 100.3. Table Injury cases are guided by statutory “Qualifications and aids in interpretation” (“QAIs”), which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. 42 CFR § 100.3(c). To be considered a “Table SIRVA,” petitioner must show:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time-frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 CFR § 100.3(c)(10). In this case, petitioner’s Table claim was already dismissed for, at a minimum, failing to meet the third of these requirements. (ECF No. 28.)

To alternatively show actual causation or “causation in fact,” petitioner must satisfy the “preponderance of the evidence” standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1279 (Fed. Cir. 2005); *Hines v. Sec’y of Health & Human Servs.*,

940 F.2d 1518, 1525 (Fed. Cir. 1991). Under that standard, the petitioner must show that it is “more probable than not” that the vaccination caused the alleged injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause of the injury or condition but must demonstrate that the vaccination was a “substantial factor” and a “but for” cause. *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). This standard has been interpreted to require “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;” the logical sequence must be supported by “reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony.” *Althen*, 418 F.3d at 1278; *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner may not receive a Vaccine Program award based solely on his or her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1); § 300aa-11(c).

In what has become the predominant framing of this burden of proof, the *Althen* court described the “causation-in-fact” standard, as follows:

Concisely stated, *Althen*’s burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If *Althen* satisfies this burden, she is “entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine.”

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner’s causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id.* at 1279-80. That expert’s opinion must be “sound and reliable.” *Boatmon v. Sec’y of Health & Human Servs.*, 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). The *Althen* court also indicated, however, that a Program fact finder may rely upon “circumstantial evidence,” which the court found to be consistent with the “system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.” *Althen*, 418 F.3d at 1280. Once a petitioner has established a *prima facie* case, the burden then shifts to respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen*, 418 F.3d at 1278 (citation omitted); § 300aa-13(a)(1)(B).

II. Procedural History

As noted above, petitioner initially asserted a Table injury. (ECF No. 1.) The case was assigned to the Chief Special Master as part of the Special Processing Unit or “SPU.” (ECF Nos. 8-9.) Petitioner filed an affidavit and medical records marked as Exhibits 1-13. (ECF Nos. 1, 17, 19.) A Statement of Completion was filed on April 27, 2021. (ECF No. 20.)

Respondent filed his Rule 4 Report on October 18, 2021. (ECF No. 23.) Regarding any Table claim, respondent argued (1) that petitioner's pain and reduced range of motion was not limited to the affected shoulder, (2) that the record is not consistent regarding the requisite period of onset, and (3) that petitioner's condition is otherwise explained by carpal tunnel syndrome. (*Id.* at 7-8.) Regarding causation-in-fact, respondent argued the record cannot support petitioner's claim absent an expert report. (*Id.* at 8-10.)

Thereafter, the Chief Special Master issued an Order to Show Cause why petitioner's Table claim should not be dismissed. (ECF No. 24.) The Chief Special Master afforded petitioner an opportunity to amend his petition to include a cause-in-fact claim, which he did. (*Id.*; see also ECF No. 25.) Petitioner then consented to dismissal of his Table claim. (ECF No. 26.) After petitioner's Table claim was dismissed (ECF No. 28), the case was reassigned to the undersigned (ECF Nos. 29-30).

Petitioner filed an expert report to support his cause-in-fact claim in August of 2022. (ECF No. 33; Exs. 14-36.) Respondent filed responsive expert reports in November of 2022. (ECF Nos. 35-36; Exs. A-B.) Thereafter, petitioner requested an opportunity to file a supplemental report by his expert and to then brief the question of his entitlement to compensation. (ECF No. 37.)

Petitioner filed a supplemental expert report on February 7, 2023 (ECF No. 38; Ex. 37) and a brief pursuant to Vaccine Rule 8(d) on February 21, 2023. (ECF No. 40.) Respondent filed a responsive brief accompanied by a supplemental report by one of his experts. (ECF Nos. 41-42; Ex. C.) Petitioner filed a reply on May 3, 2023. (ECF No. 43.)

In light of the above, I have determined that the parties have had a full and fair opportunity to present their cases and that, given the parties' assent, it is appropriate to resolve entitlement on the existing record. See Vaccine Rule 8(d); Vaccine Rule 3(b)(2); see also *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record"). Accordingly, this matter is now ripe for resolution.

III. Factual History

a. As Reflected in the Medical Records

Petitioner was 59 years old at the time of the vaccination at issue, which was administered in his right shoulder on September 20, 2017, at a primary care provider appointment. (Ex. 1, p. 6.) At that time, he was presenting for evaluation of coughing up blood as well as reporting left elbow tenderness that was likely due to soft tissue calcifications as observed on x-ray. (*Id.* at 6-9; Ex 2, p. 40.) Prior to the vaccination, petitioner also had a history of intermittent right elbow pain. (Ex. 9, pp. 6-8.)

Three days later, petitioner's wife called the primary care provider to report that petitioner was experiencing a vaccine reaction. (Ex. 3, pp. 8-9.) Petitioner was reportedly negative for a number of symptoms of a vaccine reaction, such as fever, shortness of breath, or disorientation. (*Id.* at 8.) The "main symptom" reported was "twitching to the arm" with additional bumps and itching around the injection site. (*Id.*) Petitioner reportedly denied any pain but did report stiffness. (*Id.* at 9.) Petitioner was advised to use a cold compress and Tylenol as needed and to follow up if symptoms did not resolve. (*Id.*) Approximately two months later, on November 30, 2017, a further call from petitioner's wife was documented. (Ex. 2, p. 45.) She was seeking to have petitioner's next primary care appointment advanced for several reasons, including "after 2 months, he is still having trouble with his right arm, that began after his flu shot. His fingers still tingle and go numb if he does not move his hand and fingers." (*Id.*)

Petitioner was seen by his primary care provider for "arm pain" on December 18, 2017. (Ex. 2, pp. 48-49.) On exam, petitioner had adequate grip and his radial pulses and sensation were intact in his right upper extremity. (*Id.* at 48.) However, he had paresthesia of the right upper extremity the differential diagnosis for which was "reportedly post injection vs cervical radiculopathy." (*Id.* at 49.) An EMG was ordered. (*Id.*) Petitioner presented for his EMG on January 18, 2018, with a pre-procedure diagnosis of paresthesia of the right upper extremity. (Ex. 4, pp. 6-8.) The history indicates petitioner presented "with complaints of numbness in the thumb, index and middle finger since a flu shot last fall. Brief neurological exam shows normal strength and reflexes in the upper extremities." (*Id.* at 8.) The study demonstrated "mild median neuropathy at the wrists bilaterally, worse on the right" with no evidence of denervation. (*Id.*) The day after petitioner's EMG, his wife called his primary care provider seeking "something for pain of right arm." (Ex. 2, p. 54.) She noted that he cannot sleep. (*Id.*) The assessment following the EMG was that petitioner had bilateral carpal tunnel syndrome, though without any "prominent" abnormalities, unrelated to his vaccine injection. (*Id.*; Ex. 4, p. 6.) A wrist split was recommended and gabapentin was prescribed for nerve pain. (Ex. 2, p. 54.)

About four months later, petitioner's wife called his primary care provider seeking a referral for an orthopedic evaluation. (Ex. 2, p. 65.) She explained that petitioner's right shoulder had been bothering him since September. (*Id.* at 64.) The requested referral was provided. (*Id.*) Petitioner then saw an orthopedist on June 6, 2018. (Ex. 5, pp. 15-18.) At that time petitioner complained of severe right shoulder pain, increasing with reaching, that began 8 months prior. (*Id.* at 15.) Petitioner did not complain of instability or weakness. (*Id.*) Upon physical exam, petitioner was negative for any acromioclavicular joint or biceps tenderness but was positive for subacromial space tenderness. (*Id.* at 17.) He had a positive cross body test and signs of subacromial impingement. (*Id.*) External rotation was 25 degrees and petitioner could reach L1 on internal rotation. (*Id.*) Light touch was intact. (*Id.*) X-ray showed no glenohumeral arthritis but did show changes suggestive of chronic tendonitis. (*Id.*) Petitioner was diagnosed with rotator cuff tendonitis. (*Id.*) A follow up ultrasound and a cortisone injection were recommended. (*Id.*)

Petitioner underwent an ultrasound of his right shoulder on August 24, 2018. (Ex. 6, pp. 7-8.) Petitioner had a mild amount of fluid in his biceps tendon and his subscapularis tendon had thickening consistent with tendinosis, without evidence of a tear. (*Id.* at 7.) His supraspinatus tendon had a full thickness tear with a bony irregularity. (*Id.*) His subacromial bursa was minimally thickened. (*Id.*) He had mild acromioclavicular osteoarthritis. (*Id.*) There was no sizeable glenohumeral effusion. (*Id.*) A dynamic evaluation showed normal range of motion and no evidence of subacromial or subcoracoid impingement. (*Id.*) The impression was full-thickness tear of the supraspinatus tendon, subscapularis tendinosis without a tear, and mild acromioclavicular joint osteoarthritis. (*Id.*)

Petitioner began physical therapy for chronic right shoulder pain about two weeks later. (Ex. 5, pp. 30-35.) Petitioner presented with limited function due to his right shoulder full thickness rotator cuff tear. (*Id.* at 30.) In particular, he complained of difficulty with sleeping and lifting. (*Id.* at 32.) He complained of “R shoulder pain that began about a year ago. It began after a flu shot.” (*Id.*) His pain is characterized as intermittent and radiating to the upper arm. (*Id.*) He also reported having numbness and tingling in his first three digits. (*Id.*) Upon evaluation, petitioner had range of motion within functional limits and with no increase in pain. (*Id.* at 33.) He had normal strength, but pain with resisted abduction and tenderness to palpation. (*Id.*) Light touch sensations and reflexes were within normal limits. (*Id.* at 34.) Cervical spinal and shoulder special tests were all negative. (*Id.* at 34.) It was noted that petitioner had a stable and uncomplicated presentation with good rehab potential, but that he had poor understanding of his condition and poor self-management skills. (*Id.* at 31.) The goals of physical therapy were to decrease pain, increase flexibility, posture, and stabilization. (*Id.* at 31.) Twelve sessions over eight weeks were recommended. (*Id.*)

On November 1, 2018, petitioner contacted his primary care provider seeking pain medication for ongoing shoulder pain he attributed to his vaccination. (Ex. 2, p. 68.) He was prescribed a muscle relaxant. (*Id.*) However, shortly thereafter, on November 12, 2018, he presented to the emergency department with a complaint of “right arm pain that has been ongoing for one year,” and which he again attributed to his flu vaccination, though the record misstates that the vaccination was administered in December. (Ex. 13, pp. 8-9.) Petitioner reported that his pain was located in his right shoulder, arm, and hand. (*Id.* at 9.) He indicated it was waxing and waning, shooting and sharp, and radiated to his fingers. (*Id.*) The pain was reportedly worsened by movement and relieved by nothing. (*Id.*) Petitioner also had numbness and decreased sensation in a medial distribution but had normal range of motion of the shoulder. (*Id.* at 11.) Both he and his wife asserted that the carpal tunnel diagnosis was unlikely because petitioner had no reason to have carpal tunnel syndrome, and both were “adamant” that his condition resulted from the flu vaccination. (*Id.* at 12.) The emergency physician felt petitioner had signs and symptoms consistent with neuromuscular right arm pain and expressed suspicion regarding “RSD” (presumably rejection sensitive dysphoria) but diagnosed only “pain of right upper extremity.” (*Id.* at 11-12.) Petitioner returned to his primary care provider two days later, on November

14, 2018, for chronic right arm pain that he indicated started “the next day” following his flu vaccination. (Ex. 2, p. 74-75.) He was referred to neurology and a pain clinic given his pain and paresthesia. (*Id.* at 75.)

Petitioner also saw his orthopedist on November 14, 2018. (Ex. 5, pp. 65-69.) Petitioner complained of persistent right shoulder pain that he attributed to his flu vaccination. (*Id.* at 65-66.) In particular, petitioner complained of pain worse at night and with reaching. (*Id.* at 65.) The orthopedist re-reviewed the prior EMG and confirmed it showed only evidence of carpal tunnel syndrome but noted that it did not examine the axillary nerve, which could reveal a radiculopathy. (*Id.*) Absent that, the orthopedist’s “working diagnosis” remained rotator cuff tear. (*Id.* at 66.) He ordered a follow up EMG of the axillary nerve to clarify the diagnosis and to have further follow up after that. (*Id.* at 69.) The axillary nerve EMG was normal. (Ex. 4, pp. 9-11.)

Petitioner did not return for follow up care until October of 2019. (Ex. 12, pp. 194-95.) (In the interim, petitioner pursued physical therapy for a left shoulder injury related to a fall. (*Id.* at 170-71.)) The orthopedist attributed the lack of follow up after the axillary nerve EMG to a miscommunication. (*Id.* at 194.) Petitioner had no numbness or tingling and had full range of motion, but with some discomfort and some impingement with abduction. (*Id.*) It was noted that petitioner was able to do heavy lifting, but that he continued to have difficulty with overhead reaching. (*Id.* at 95.) The orthopedist’s final diagnosis was supraspinatus rotator cuff tear for which he recommended surgery. (*Id.*) It was also suggested that petitioner seek a second opinion. (*Id.*) The second orthopedist to whom petitioner was referred ordered a right shoulder MRI, which was completed on November 12, 2019. (*Id.* at 210-11.) The impression was (1) moderate to significant diffuse rotator cuff tendinosis involving the supraspinatus and infraspinatus tendon with a full-thickness tear of the anterior supraspinatus; (2) significant subscapular tendinosis with fraying; (3) significant proximal long head biceps tendinosis; and (4) mild degenerative acromioclavicular joint and glenohumeral joint osteoarthritis. (*Id.* at 211.) However, no further treatment records were filed.

b. As Reflected in Petitioner’s Affidavit

Petitioner avers that he had not suffered any injury to his right shoulder prior to administration of the flu vaccination at issue. (Ex. 11, ¶ 5.) He states:

The day after receiving the vaccine, I told my wife that my right arm didn’t feel right. My arm was painful and stiff, and it felt like my muscle was “jumping.” On September 23, 2017, my wife spoke to a nurse at Henry Ford Medical Center and relayed my symptoms. We were told to apply a warm compress on the muscle where it was twitching.

(*Id.* at ¶ 4.)

Petitioner indicates that he continues to experience pain and reduced strength in his right arm. (*Id.* at ¶ 7.)

IV. Expert Reports

a. Petitioner's expert, Naveed Natanzi, D.O.³

Dr. Natanzi cites several medical records which he indicates support onset of “an atypical sensation and pain in [petitioner's] shoulder beginning the day after vaccination.” (Ex. 14, p. 7 (citing Ex. 3, p. 8; Ex. 2, pp. 48, 74; Ex. 5, p. 15).) Whereas petitioner had no prior history of right shoulder complaints, his post-vaccination presentation included difficulty reaching, pain upon palpation, and impingement. (*Id.* (citing Ex. 5, p. 15; Ex. 12, p. 19).) MRI confirmed a rotator cuff tear, which Dr. Natanzi indicates is commonly seen in SIRVA. (*Id.* (citing Ex. 13, p. 211).) Dr. Natanzi agrees that petitioner also suffered carpal tunnel syndrome that arose independent of his vaccination and that resulting injury. (*Id.* at 7-8.) He asserts that this explained petitioner's discomfort in his right hand. (*Id.* at 8.) Dr. Natanzi does not assert that vaccination in the shoulder can cause carpal tunnel syndrome. (*Id.*) Conversely, “there is no way [carpal tunnel syndrome] can be the cause of [petitioner's] shoulder pain . . . [q]uite simply, the presence of [carpal tunnel syndrome], which is an issue of the wrist, has no bearing on the possibility of a vaccine needle over-penetrating its target and causing a shoulder injury.” (*Id.*) Dr. Natanzi opines that petitioner's injury meets both the Table criteria for SIRVA and also the three-part *Althen* test for determining causation-in-fact. (*Id.* at 9-10.)

To the extent that respondent's orthopedic expert, Dr. Cagle, asserts that carpal tunnel syndrome can sometimes cause shoulder pain, Dr. Natanzi charges that the evidence supporting that assertion (two case series) is “weak.” (Ex. 37, p. 1 (discussing Yusuke Hagiwara, et al, “*Idiopathic Shoulder Pain and Dysfunction from Carpal Tunnel Syndrome and Cubital Tunnel Syndrome*, 10 PLASTIC RECONSTRUCTIVE SURGERY: GLOB. OPEN e4114 (2022) (Ex. B, Tab 2); Bertram M. Kummel & George A. Zazani, *Shoulder Pain as the Presenting Complaint in Carpal Tunnel Syndrome*, 92 CLINICAL ORTHOPAEDICS & RELATED RESEARCH 227 (1973) (Ex. B, Tab 3)).) Moreover, the larger series cited by Dr. Cagle (Hagiwara, et al., *supra*, at Ex. B, Tab 2) screened out patients with MRI evidence of shoulder pathology such as rotator cuff tear. (Ex. 37, p. 2.) Thus, he contends that this hypothesis does not accord with petitioner's own history. (*Id.* at 1-2.) Specifically, Dr. Natanzi stresses the post-vaccination timing of onset for the shoulder pain and also disagrees that the observed rotator cuff tear was asymptomatic given the history and physical exam. (*Id.* at 1 (citing Ex. 5, p. 15; Ex. 12, p. 19).) If Dr.

³ Dr. Naveed Mayer Natanzi received his doctorate in osteopathy from Western University of Health Sciences. (Ex. 15, p. 2.) He is board certified in physical medicine and rehabilitation. (*Id.* at 1.) He currently works as a physician at VA Long Beach Healthcare System and is an attending physician at Pasadena Rehab Institute. (*Id.*) He is also the founder of the Regenerative Sports and Spine Institute. (*Id.*) He has written and sought publication for seven articles and has participated in the development of two research studies. (*Id.* at 3-4.)

Cagle's proposed explanation was correct, one would expect a gradual onset, the lack of any inciting event, and moderate to severe carpal tunnel based on EMG. (*Id.* at 1.)

b. Respondent's expert, Pria Anand, M.D. ⁴

Dr. Anand's report has the primary purpose of confirming petitioner's carpal tunnel syndrome diagnosis and that his symptoms of paresthesias and numbness of his hand and fingers are due to that condition. (Ex. A, p. 5.) Dr. Anand does not assert that carpal tunnel syndrome would explain symptoms of shoulder pain; however, she doubts that the medical records support an immediate post-vaccination onset of shoulder pain. (*Id.*) She notes that SIRVA is not the only possible etiology for the type of pathologies observed on petitioner's MRI. (*Id.*) Dr. Anand concludes that petitioner's initial complaints that his arm "just didn't feel right" and "my muscle was 'jumping'" or "twitching and itching around site as well as some stiffness," are not consistent with the shoulder pain typically observed in SIRVA. (*Id.* at 4 (citing Ex. 11, p. 1; Ex. 3, p. 8).)

c. Respondent's expert, Paul Cagle, M.D. ⁵

Dr. Cagle indicates that petitioner's presentation "clearly demonstrates a picture of neurologic changes along the arm." (Ex. B, p. 3.) He further notes that petitioner's EMG confirmed the diagnosis in the wrist, but a subsequent EMG of the shoulder did not demonstrate shoulder axillary nerve involvement. (*Id.*) Therefore, petitioner's medical history presents a condition isolated to the wrist rather than any shoulder injury. (*Id.*) Dr. Cagle acknowledges that a rotator cuff tear was also diagnosed, but opines that it was most likely an incidental, asymptomatic finding. (*Id.* at 4.) Dr. Cagle cites literature that he asserts demonstrates that carpal tunnel syndrome can present with shoulder pain. (*Id.* (citing Hagiwara, et al, *supra*, at Ex. B, Tab 2; Kummel & Zazani, *supra*, at Ex. B, Tab 3)).) Because Dr. Cagle opines that only carpal tunnel syndrome is present, he limits his discussion of vaccine causation to that condition. He opines there is no scientific link between vaccination and carpal tunnel syndrome. (*Id.*) He observes that the treating physicians characterized petitioner's carpal tunnel syndrome as "not apparently related to injection." (*Id.* (citing Ex. 2, p. 56).)

In response to Dr. Natanzi's criticism of the Hagiwara and Kummel and Zazani papers as "weak" evidence, Dr. Cagle counters that the case series examined are comparable in scale to much of the available SIRVA literature. (Ex. C, p. 1.) He further

⁴ Dr. Pria Anand received her medical degree from Stanford University School of Medicine. (Ex. A, Tab 5, p. 1.) She is board certified in psychiatry and neurology. (*Id.*) She is currently an assistant professor in the Department of Neurology at Boston Medical Center at Boston University. (*Id.*) She has written 23 peer reviewed articles and one textbook chapter, and submitted seven editorials, seven reviews, and six case reports for publication. (*Id.* at 9-12.)

⁵ Dr. Paul J. Cagle Jr. received his medical degree from Loyola University Stritch School of Medicine in Chicago. (Ex. B, Tab 8, p. 1.) He is board certified in orthopaedic surgery and currently works as an associate professor at the Icahn School of Medicine in the Leni and Peter May Department of Orthopedics located in Mount Sinai. (*Id.*) He has published 60 peer reviewed articles and eight book chapters. (*Id.* at 3-10.)

stresses that Dr. Natanzi has not identified any conflicting literature. (*Id.*) By contrast, the literature demonstrates that asymptomatic rotator cuff tears are “a common occurrence” and “the simple presence of a rotator cuff tear does not indicate an injury or even a painful condition.” (*Id.* at 2.)

V. Discussion

a. *Althen* prong one

Under *Althen* prong one, petitioner must provide a “reputable medical theory,” demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (citations omitted). Such a theory must only be “legally probable, not medically or scientifically certain.” *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994). Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1325-26 (Fed. Cir. 2006)). However, “[a] petitioner must provide a ‘reputable medical or scientific explanation’ for [her] theory. While it does not require medical or scientific certainty, it must still be ‘sound and reliable.’” *Boatmon*, 941 F.3d at 1359 (quoting *Knudsen*, 35 F.3d at 548-49).

Petitioner argues that her expert, Dr. Natanzi, has “articulated a logical medical theory causally connecting the September 20, 2017 flu vaccination to the resulting SIRVA-type injury. Dr. Natanzi describes a mechanism involving inadvertent overpenetration of the vaccination needle leading to an injury to the rotator cuff and inflammatory response, eventually leading to inflammation and pain in the rotator cuff tendons.” (ECF No. 40, p. 8 (citing Ex. 14, p. 8).) Petitioner also requests that the undersigned take judicial notice of respondent’s addition of SIRVA to the Vaccine Injury Table. (*Id.* (citing *Doe 21 v. Sec’y of Health & Human Servs.*, 88 Fed Cl. 179, 198 (2009), *rev’d on other grounds*, 527 F.App’x. 875 (Fed. Cir. 2013).)

In response, respondent argues that petitioner cannot succeed based on a “generic shoulder injury” and that respondent did not concede *Althen* prong one when he added “SIRVA” to the Vaccine Injury Table. (ECF No. 42, pp. 7-11.) Respondent argues it would be inappropriate to simply credit Dr. Natanzi’s *ipse dixit* and that his experts are better qualified to opine on the issues in this case. (*Id.* at 11-15.) Under the heading of “medical theories,” respondent acknowledges that petitioner’s expert theorizes a direct causal relationship between needle overpenetration and rotator cuff injury; however, respondent’s only response is to stress that her experts disclaim the presence of any actual rotator cuff injury. (*Id.* at 15-17.)

Based on my review of the record as a whole, Dr. Natanzi’s assertion that vaccine injection can lead to rotator cuff injury is not limited to his *ipse dixit*. Rather, he has cited several publications that have included rotator cuff tear and tendonitis among

the constellation of injuries that have been observed post-vaccination. (See Marko Bodor & Enoch Montalvo, *Vaccination-Related Shoulder Dysfunction*, 25 VACCINE 585 (2007) (Ex. 22); S. Atanasoff et al., *Shoulder Injury Related to Vaccine Administration (SIRVA)*, 28 VACCINE 8049, 8050, 8051 (2010) (Ex. 16, p. 3); Naveed Natanzi, Frank Hebroni, & Marko Bodor, *Teres Minor Injury Related to Vaccine Administration*, 15 RADIOLOGY CASE REP. 552, 553 (2020) (Ex. 35, p. 2). For example, Atanasoff, et al, observed that

Although shoulder dysfunction due to mechanical or overuse injury is always a diagnostic consideration, the rapid onset of pain with limited range of motion following vaccination in our series of patients is consistent with a robust and prolonged immune response within already-sensitized shoulder structures following injection of antigenic substance into the subacromial bursa or the area around the rotator cuff tendon. . . . In general, chronic shoulder pain with or without reduced shoulder joint function can be caused by a number of common conditions including impingement syndrome, rotator cuff tear, biceps tendonitis, osteoarthritis and adhesive capsulitis. In many cases, these conditions may cause no symptoms until provoked by trauma or other events Reilly et al. reviewed a series of shoulder ultrasound and MRI studies obtained in asymptomatic persons past middle age and found partial or complete rotator cuff tears in 39% of those individuals. Therefore, some of the MRI findings in our case series, such as rotator cuff tears, may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation.

(Atanasoff et al., *supra*, at Ex. 16, p. 3.)

While respondent contests whether such conditions were actually present in this case, those arguments are not germane to petitioner's particular burden of proof under *Althen* prong one. Setting petitioner's own history aside for purposes of general causation under *Althen* prong one, nothing in respondent's brief or his experts' opinions challenges that vaccination needle overpenetration *can cause* an inflammatory response that leads to symptomatic rotator cuff injury. Thus, Dr. Natanzi's actual medical theory remains unrebutted on this record. Accordingly, petitioner has satisfied *Althen* prong one.

b. *Althen* prong two

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148. In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1382-83; *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1280) (stating that "medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a

‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury’”). However, medical records and/or statements of a treating physician’s views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. See § 300aa-13(b)(1) (providing that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”); *Snyder v. Sec’y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (stating that “there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted”). Ultimately, petitioner may support her claim either through her medical records or by expert opinion. See § 300aa-13(a)(1).

Petitioner stresses that he had no prior history of shoulder pain and that just three-days post vaccination he complained (via his wife) of symptoms such as muscle twitching and stiffness around his injection site. (ECF No. 40, p. 9.) Although a nerve injury was initially suspected, treatment of that condition did not resolve petitioner’s pain and he ultimately sought an orthopedic assessment that confirmed a right shoulder injury. (*Id.*) Petitioner never wavered during treatment of his shoulder injury in dating his shoulder pain back to his vaccination and, as his expert opines, it would not be logical to blame his shoulder pain on his separately diagnosed carpal tunnel syndrome. (*Id.* at 9-10.)

Respondent argues that carpal tunnel syndrome is the only condition petitioner suffered and that all three experts opining for both parties agree that carpal tunnel syndrome would not have been caused by vaccination. (ECF No. 42, p. 18.) Respondent stresses Dr. Anand’s opinion that petitioner’s initially reported symptoms were not typical of SIRVA as well as Dr. Cagle’s opinion that “the simple presence of a rotator cuff tear does not indicate an injury or even a painful condition.” (*Id.* (quoting Ex. C, p. 2).) Respondent argues that Dr. Cagle’s explanation of carpal tunnel syndrome leading to shoulder pain is more credible than Dr. Natanzi’s invocation of two separate conditions, namely carpal tunnel syndrome and a separate rotator cuff injury. (*Id.* at 15-16.)

The nature and timing of onset of petitioner’s reported post-vaccination symptoms is separately discussed under *Althen* prong three. However, even if finding petitioner has met his burden under *Althen* prong three, respondent would still argue that petitioner’s condition is explained solely by carpal tunnel syndrome, for which there is no opinion supporting vaccine causation. (ECF No. 40, pp. 17-19.) Respondent is unpersuasive in arguing that petitioner’s carpal tunnel syndrome diagnosis precludes him from demonstrating a logical sequence of cause and effect between his vaccination and his shoulder injury.

First, respondent’s view is in conflict with the contemporaneous medical records. Petitioner’s orthopedist diagnosed a right shoulder condition, and ultimately recommended surgery, with full knowledge that petitioner had also been previously diagnosed with carpal tunnel syndrome. (Ex. 12, p. 195.) Although asymptomatic

rotator cuff pathology can sometimes be revealed incidentally on imaging, petitioner's diagnosis was not based solely on imaging. Petitioner was seeking treatment for shoulder pain and his orthopedist also conducted a physical exam and took a history that he concluded was indicative of a rotator cuff pathology. (Ex. 5, p. 17.) While respondent's expert, Dr. Cagle, stresses that it is possible for rotator cuff pathology to be asymptomatic, neither of respondent's experts address the basis for the treating orthopedist's actual diagnosis *in this case*. (Ex. B, p. 4.)

Additionally, petitioner's presentation is not necessarily consistent with what Dr. Cagle hypothesizes. While respondent is persuasive in contending that carpal tunnel syndrome can sometimes cause radiating pain, Dr. Natanzi is persuasive in observing that the Hagiwara case series hypothesized only that carpal tunnel syndrome may explain *idiopathic* shoulder pain. (Hagiwara, et al, *supra*, at Ex. B, Tab 2, p. 1.) In that regard, Hagiwara, et al., explicitly precluded any patient with any evidence of rotator cuff pathology. (Hagiwara, et al., *supra*, at Ex. B, Tab 2, p. 2.) Moreover, in both the Kummel and Zazanis and Hagiwara papers, carpal tunnel syndrome is hypothesized as the cause of shoulder pain because treatment of the carpal tunnel syndrome relieved symptoms, including those of the shoulder. (Kummel & Zazanis, *supra*, at Ex. B, Tab 3; Hagiwara et al., *supra*, at B, Tab 2.) Here, however, there is no evidence that any such phenomenon occurred. Petitioner was first treated for carpal tunnel syndrome and a shoulder pathology was explored only after petitioner complained that treatment for his carpal tunnel syndrome mainly gabapentin for neuropathic pain, did not provide relief.⁶ (Ex. 2, pp. 52-53, 64.)

Kummel and Zazanis explain that shoulder pain related to carpal tunnel syndrome is a relatively rare presentation, with only 15% of patients' carpal tunnel syndrome patients reporting pain radiating antidromically toward the neck and shoulder. (Kummel & Zazanis, *supra*, at Ex. B, Tab 3, p. 1.) Notably, while respondent's orthopedist, Dr. Cagle, opines that petitioner's carpal tunnel syndrome may explain his shoulder symptoms, respondent's neurologist, Dr. Anand, conspicuously did not reach any similar conclusion. To the extent Dr. Anand questions whether petitioner's earliest symptoms, inclusive of "stiffness" are consistent with a SIRVA-like presentation, the literature filed in this case indicates that rotator cuff lesions are "one of the most common known causes of secondary stiffness." (Zein M. Saleh, Sami Faruqui, & Abdullah Foad, *Onset of Frozen Shoulder Following Pneumococcal and Influenza Vaccinations*, 14 J. CHIROPRACTIC MED. 285, 288 (2015) (Ex. 25, p. 4).)

In light of the above, respondent is not persuasive in contending that petitioner's right shoulder pain should be attributed to carpal tunnel syndrome instead of his confirmed rotator cuff pathology. Accordingly, petitioner's lack of any prior history of shoulder pain, his separate showings under *Althen* prongs one and three, and Dr. Natanzi's further supporting causal opinion supporting a logical sequence of cause and

⁶ In addition to pain medication, petitioner was recommended to wear a wrist brace. However, he later reported that he did not wear the wrist brace because he did not think the diagnosis of carpal tunnel syndrome was correct. (Ex. 13, p. 12.)

effect, are sufficient for petitioner to meet his burden of proof under *Althen* prong two by preponderant evidence.

c. *Althen* prong three

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1278. A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact.” *de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). In this case, petitioner’s expert, Dr. Natanzi, opines that it is medically reasonable to infer vaccine causation where onset of symptoms occurs within 48 hours of vaccination, the same period utilized by the Vaccine Injury Table for SIRVA. (Ex. 14, p. 10.) Respondent’s experts effectively agree. (Ex. A, p. 4; Ex. B, p. 4.)

Petitioner argues that respondent has raised no concern regarding the onset of his symptoms. (ECF No. 40, p. 10.) Petitioner contends that his repeated attributions of his pain to his vaccination are sufficient to evidence that onset was within 48 hours of vaccination. (*Id.* (citing *Williams v. Sec’y of Health & Human Servs.*, No. 17-1046V, 2020 WL 3579763, at *5 (Fed Cl. Spec. Mstr. Apr. 1, 2020).) However, in his motion response, respondent does challenge onset, arguing that petitioner’s initial symptom complaints (made via his wife) were muscle stiffness and twitching as well as numbness and tingling in the right hand and finger, which were instead attributable to his carpal tunnel syndrome. (ECF No. 42, pp. 20-21 (citing Ex. A, pp 4-5; Ex. B, pp. 4-5).) Thus, he contends the evidence indicates there was no shoulder pain within 48 hours of vaccination. (*Id.* at 20.)

Respondent raises an important point in noting that petitioner’s earliest reported medical histories do not indicate that petitioner was experiencing shoulder pain. (ECF No. 42, p. 20 (citing Ex. 3, pp. 8-9; Ex. 2, p. 45).) In particular, the first report of a vaccine reaction, offered three days post-vaccination, explicitly denied petitioner was experiencing any pain. (Ex. 3, p. 9.) However, these first two reports deserve less weight than a contemporaneous record would normally receive, because the description of symptoms was offered by petitioner’s wife over the telephone. Thus, the resulting record does not memorialize any direct communication between petitioner and his physician. While petitioner avers in his affidavit that his initial presentation included pain, he explains that he much more vaguely “told [his] wife that [his] right arm didn’t feel right.” (Ex. 11, ¶ 4.) In that regard, the record does seem to reflect that petitioner struggled to articulate what he was experiencing. The evidence reflects petitioner resorting to vague or colloquial expressions of his symptoms, such as his shoulder being “not right” or “jumping” and his physical therapist recorded that he had a poor understanding of his own condition. (Ex. 3, p. 9; Ex. 11, Ex. 5, pp. 31.)

In contrast, when petitioner did first present to his primary care provider in person for these complained of post-vaccination symptoms, arm pain was specifically recorded

and the resulting differential diagnosis was between a post injection phenomenon or cervical radiculopathy, both of which potentially implicate shoulder pain. (Ex. 2, p. 49.) Thereafter, when petitioner himself presented for care, the records were clearer in capturing that he was suffering shoulder pain that began after vaccination. (Ex. 4, pp. 6-8; Ex. 5, p. 32, 65; Ex. 2, p., 74; Ex. 13, pp. 8-9.) That the first such report of shoulder pain occurred a little over two months post-vaccination is not in itself unusual. See *Flores v. Sec'y of Health & Human Servs.*, No. No. 20-1858V, 2023 WL 4248571, at *5 (Fed. Cl. Spec. Mstr. May 24, 2023) (granting entitlement based on a Table claim and finding that petitioner reported his pain more than two months post-vaccination which was “not immediately, but not wholly attenuated and untimely”); *Davenport v. Sec'y of Health & Human Servs.*, No. 20-206V, 2023 WL 8598645, at *4 (Fed. Cl. Spec. Mstr. Nov. 8, 2023) (granting entitlement based on a Table claim and finding that even though petitioner first sought treatment “approximately two months after vaccination,” there was preponderant evidence that petitioner’s pain began 48 hours after vaccination based on medical records that “consistently link his shoulder pain” to his vaccination); *Hutchens v. Sec'y of Health & Human Servs.*, No. 17-797V, 2021 WL 4267579 (Fed. Cl. Spec. Mstr. Aug. 31, 2021) (finding that petitioner preponderantly established that his pain began the day of his vaccination, even though he did not report pain to a doctor until two months after his vaccination). Considered as a whole, petitioner’s medical treatment records support that he started experiencing what he perceived as a vaccine reaction within hours to a day after his vaccination (Ex. 3, p. 8; Ex. 2, pp. 49, 74; Ex. 4, pp. 6-8; Ex. 5, pp. 32, 65; Ex. 13, pp. 8-9; Ex. 11, ¶ 4) and that, while the exact nature of this condition was not clearly expressed, it did include shoulder pain and stiffness from the outset. (Ex. 3, p. 9; Ex. 2, pp. 49, 54.)

In light of the above, I conclude that petitioner has satisfied *Althen* prong three by preponderant evidence.

d. Factor Unrelated

Once petitioner has satisfied his own *prima facie* burden, respondent has the opportunity to demonstrate, also by a preponderance of the evidence, that petitioner’s injury was nonetheless caused by a factor unrelated to vaccination. §300aa-13(a)(1)(B); § 300aa-13(a)(2); *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013). In order to meet his burden, respondent must demonstrate by preponderant evidence “that a particular agent or condition (or multiple agents/conditions) unrelated to the vaccine was in fact the sole cause (thus excluding the vaccine as a substantial factor).” *de Bazan*, 539 F.3d at 1354. As with petitioner’s burden under *Althen*, respondent must show a logical sequence of cause and effect linking the injury to the proposed factor unrelated. *Deribeaux*, 717 F.3d at 1369. It need not be scientifically certain but must be legally probable. *Id.*

Here, respondent asserts that the burden should not shift to him because petitioner has not met his own *prima facie* burden of proof. (ECF No. 42, p. 21.) Respondent stresses that he is not the burdened party and that he may offer evidence to challenge petitioner’s case in chief without taking on the burden of proof. (*Id.*)

For all the reasons discussed above, however, I have concluded that petitioner did meet his *prima facie* burden under *Althen*. Accordingly, it is necessary to additionally, albeit briefly, note that respondent did not meet his burden of proof. I have already examined under *Althen* prong two respondent's contention that petitioner's condition is explained solely by carpal tunnel syndrome. Although respondent has shown that carpal tunnel syndrome can cause shoulder pain in a minority of cases, he has not demonstrated that it would be appropriate to attribute petitioner's own shoulder symptoms to his carpal tunnel syndrome given his own clinical history. Accordingly, respondent cannot meet his shifted burden of proof.

VI. Conclusion

After weighing the evidence of record within the context of this program, I find by preponderant evidence that petitioner suffered a shoulder injury caused-in-fact by his September 20, 2017 flu vaccination. A separate damages order will be issued.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master